UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, ex rel. JULIE LONG, Plaintiffs	)	Civil Action No. 16-12182-FDS
vs. JANSSEN BIOTECH, INC., Defendant	)	

BEFORE: CHIEF JUDGE F. DENNIS SAYLOR, IV

STATUS CONFERENCE HELD BY ZOOM

John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

March 13, 2024
4:00 p.m.

Valerie A. O'Hara, FCRR, RPR
Official Court Reporter
John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210
E-mail: vaohara@gmail.com

APPEARANCES VIA ZOOM:

For The Relators:

Cohen Milstein Sellers & Toll PLLC, by CASEY M. PRESTON, ESQ., 1717 Arch Street, Suite 3610, Philadelphia, Pennsylvania 19103;

Cohen Milstein Sellers & Toll, PLLC, THEODORE JON LEOPOLD, ESQ., DIANA L. MARTIN, ATTORNEY, and POORAD RAZAVI, ESQ., 11780 US Highway One, Suite 200, Palm Beach Gardens, Florida 33408;

For the Defendant:

Covington & Burling LLP, by JASON C. RAOFIELD, ESQ., MATTHEW F. DUNN, ESQ., NICHOLAS PASTAN, ESQ., and ALISON DICIURCIO, ATTORNEY, 850 Tenth Street, NW, Washington, D.C. 20001-4956.

PROCEEDINGS

THE CLERK: Court is now in session in the matter of United States vs. Janssen Biotech, Inc., Civil Action Number 16-12182.

Participants are reminded that photographing, recording or rebroadcasting of this hearing is prohibited and may result in sanctions.

Would counsel please identify themselves for the record, starting with the plaintiff.

04:01PM MR. LEOPOLD: Good afternoon, Ted Leopold, Casey Preston, Dianne Martin, Poorad Razavi on behalf of the relator plaintiffs.

THE COURT: Good afternoon.

MR. RAOFIELD: Good afternoon, your Honor, Jason Raofield of Covington & Burling on behalf of Janssen, and I have with me Alison DiCiurcio, Nick Pastan, and Matthew Dunn. I think that's it.

THE COURT: All right. Good afternoon. This is a status conference in this case. We're conducting this by video conference. The parties have submitted a joint status report, which I reviewed, and the parties have indicated that they agree that September 30th, 2024 is an appropriate date for the completion of Phase I fact discovery, so I will order that, and pursuant to the same status report, I will permit relator to take up to 20 fact witness depositions with additional

depositions only permitted by order of the Court for good cause shown.

As I like to say, all these sorts of numbers are arbitrary. The 21st deposition will be easier to get than the 22nd one, and if you say you need 75, I'll probably cheerfully interrupt you and say no, and we'll see how this goes.

More broadly, I would like to have a plan, which we don't need to have now for the trial or other resolution of this case, and I don't know what that means or what timetable exactly, but part of that is going to be at some point before too long blocking off some time for a trial and working backwards from that because otherwise it's quite difficult to schedule.

04:03PM

So I don't necessarily need to hear that now, but I think I may order a round of submissions on that topic, what do you think, in other words, what issues do we have to address, and in what rational time frame we could get them addressed, but with that, Mr. Leopold, what is on your mind that you want to take up, never mind what's on your mind, what do you want to take up?

04:04PM

MR. LEOPOLD: Really I'd like to continue on the conversation that your Honor just raised. I think that is sort of where we are at this point. I believe it's fair to say that the parties, as you have indicated, agreed on the cutoff date for Phase I fact discovery, depositions, and I'll raise a

housekeeping matter a little bit later, but I think after the September 30th date, the parties are of the mindset that there be, which I'm sure we can work out, a time for the filing as the defendants have been saying from pretty much Day 1, filing a motion for summary judgment, and what that constitutes, and as your Honor may recall, you know, we've had these discussions at length in one hearing and generally at a few others, which is how do we handle the summary judgment?

Since the defendants have indicated, at least to us, that they intend to file a summary judgment on, quote, "everything," what does that mean? Do they go ahead and file it? How do we defend it? Should we then have -- you know, they file with their experts, and as your Honor has stated in the past, we're not sure if we're going to have experts or declarations or something else.

In our view, they should go first. I think it's their view that we should go first but yet we're not sure what all the issues are. We're finishing the, lack of a better word, "Phase I discovery," although we have, I think, completed a lot of the issues that were on the table regarding it being a national process and things of that sort, so we just sort of need to have an understanding of how the Court would like the summary judgment to go because I think that will have a lot to do with how the case proceeds thereafter.

THE COURT: All right. Who is taking the lead for

Janssen?

MR. RAOFIELD: I am, Jason Raofield, your Honor. So this case has been going on for a long time now, and I understand there have been a lot of turnover, at least on our side, in terms of the attorneys. I've been on this case for about a year. I do understand there's been a long history in this, you know, procedural history here, and I've read the transcripts of the prior hearings. I've, you know, read up on the procedural history so that I can be as familiar as possible, your Honor, and I think that what we -- our thinking is that in the last few years, there's been quite a lot of discovery that has taken place. I know your Honor hasn't been particularly involved over the course of the past year.

There have been 77 custodians that Janssen has produced documents for, and I believe we're going to be producing a few more. 71 of those are national custodians, they're not just focused on Central Pennsylvania. Of the seven depositions that have happened in the case, all seven have been national in scope, not just focused on Central Pennsylvania, so the point is just that there's been quite a lot of discovery.

The only thing, your Honor, that has not been taking place has been the sort of applied to discovery, the programs as applied in jurisdictions other than Central Pennsylvania, and we've worked cooperatively. We continue to do that, including with the filing that we made last night, your Honor.

In terms of how we think this ought to proceed, I agree with Mr. Leopold, we have a difference of opinion. In our view, it does not make sense to, and we understand that the Court asked the parties to back in 2021, anyway, to consider whether there was a way that it might make sense, might be more efficient to proceed with experts in sort of a different than the ordinary course, and we have considered that, but in our view, it's clear that that -- it won't, there's no way it will end up promoting efficiency.

04:08PM I think in particular what I could point out, your Honor, is that from our point of view we submitted to the Court a schedule that we think makes sense. It's Docket 410. We think it is a more traditional sort of approach to experts and moving on with summary judgment from there. By contrast, in Docket 411, the relator proposed something much different, and I think that if you take a look at their schedule, you can see it really makes the point that I'm trying to make, which is it doesn't actually promote efficiency, so in the schedule that they proposed in Docket 411, your Honor, they're reserving

04:08PM their right to designate their own experts, even though they're saying we should go first.

So what they proposed is kind of odd. We would file summary judgment, and Janssen at the same time would designate their experts. They then would have the ability to designate their own affirmative experts, not just rebuttal, but their own

affirmative experts, and then even according to their schedule, there would be a lengthy process for expert discovery, all of which would take place oddly over about a six-month period before they would even file their opposition to the motion for summary judgment, and I think it's clear that that would be very inefficient, for example, it's hard to imagine that we wouldn't have to refile our summary judgment motion based on what we learned from their experts that we've never heard from before we filed the summary judgment motion to begin with.

04:09PM We actually think it would also be unfair to Janssen. Relator has the burden of proof, and we should be able to understand the evidence and their positions. We shouldn't have to file summary judgment while they're reserving the right to come up with expert opinions that we don't even know what they might involve, so from our point of view, we don't think that their proposed approach would be efficient, practical, or fair, and so that's why we've submitted a proposal, your Honor, that would follow the more traditional course of fact discovery being followed by expert disclosures and discovery, and then

04:10PM summary judgment.

We just think that in the years that have happened since there were conversations about alternative ways back in 2021, this has become much more of a normal case, and whatever -- I guess the bottom line is whatever inefficiencies might result or they look a lot like the inefficiencies that

can result in any large case when fact discovery is followed by expert discovery and then summary judgment.

THE COURT: All right. What I am going to propose is the following: Those letters were sent last fall, so it's been quite awhile. I think what I would like to do is dust those off, look at those again in light of where we are now, give the parties an opportunity to supplement or propose anything different. I don't care what format it's in, but in some form or another, if you want to add to that or substitute something new, your proposal for how you think this ought to unfold including specific dates, let's do that.

If we're going to have a trial in this case, I would like to have it occur let's say next spring, a year from now. I don't think that's unrealistic, even given the size of this case, but it will, you know, require some focus that maybe the case hasn't had for awhile. That's just a target.

As you probably know, it's harder to try longer cases for a variety of reasons when you get into the summer months, and I'd rather wait a year than a year and a half, but I will be open to reason, and then I'd like to convene in about let's say four weeks or so and just set a timetable for different events. It may be less than perfect. It may need to be modified, but, just, you know, here's what we're going to do, and we'll see how the case unfolds. So that's sort of off the top of my head. Mr. Leopold.

MR. LEOPOLD: Yes, your Honor, thank you. Two issues; one substantive. As we proceed forward and as we have looked backwards and now proceeding forward towards the finishing of factual discovery, I think it's fair to say the parties are a little bit up in the air in terms of the causation issue, "but-for issue," as your Honor certainly knows. You know, this issue is up at the First Circuit.

THE COURT: Yes.

MR. LEOPOLD: And the law at this point is I guess a little bit in flux, so we're not sure in terms of how deep into discovery on this issue we need to go, A; or is it even an issue for summary judgment where we can worry or address it post-summary judgment?

THE COURT: Well, sort of implicit in my thinking there is that issue would have been resolved by then, but, you know, maybe that's optimistic, I don't know. You know, if fact discovery is not even going to close until September --

MR. LEOPOLD: Yes, but we think the briefing is closed until the end of May or June, if I'm not mistaken. I think the government is weighing in at that point.

THE COURT: Of this year, in the circuit, you're talking about?

MR. LEOPOLD: Yes, yes.

THE COURT: So obviously, you know, I don't think I can -- well, I certainly don't think I can address a motion for

summary judgment on causation issues until I know what the law is, okay? I think that's pretty fair, and I don't want you to brief it either. I think there are other things we can accomplish, what the time frame of that is I don't know, but even if I delayed expert discovery until after -- fact discovery and set a deadline for summary judgment, that briefing wouldn't be until next fall anyway. I mean, that's like the earliest it's going to occur, so I don't know. That's what I say, this could -- there are a lot of moving parts here, and this could go in a lot of different directions, but --

04:14PM

MR. LEOPOLD: Well, I think as long as -- if I understood your Honor, you know, at this point since the law is somewhat in flux, we don't need to brief it and/or at this point do -- which could potentially detail a lot of the discovery, depending how the First Circuit rules on that particular issue of causation until we know how the law comes out.

THE COURT: Well, I don't know how fact discovery would really be affected. I'm struggling to think how your deposition questions would be different depending on what that standard is. You know, the legal consequences of those decisions might be different, and, again, there's this whole issue of the medical --

04:15PM

MR. LEOPOLD: Right.

THE COURT: -- you know, decisions, I suppose, but

within the company, it seems to me that nothing really changes.

MR. RAOFIELD: Your Honor, Jason Raofield. I agree, and I think it's important that we not have any ambiguity. I totally hear everything about what things will look like with experts and summary judgment and trial, but I think it's important that it's clear that we are proceeding with fact discovery regardless, right, proceed with discovery on whatever the causation standard may turn out to be. You're going to do discovery and do it once.

04:16PM THE COURT: Well, yes. I mean, I say yes cavalierly, maybe is really the right answer. It seems to me that discovery as to what happened internally in the company is largely going to be unaffected by this. Again, I could be missing something. To what extent, depending what the standard is, decisions of specific medical providers may be involved here. You know, I don't know where we go with that, okay, I don't know. I don't want to think about that and hear from the parties, so the answer is a big fat maybe.

If the First Circuit agrees with my analysis, it's

04:16PM going to go down one path, if they disagree with me, it will go down another path, but what I want to do, I guess, is set a timetable that I can move later as opposed to just simply drifting, and I don't want you to waste your time, I don't want things to be inefficient, I don't want you to brief issues where the law is unresolved if it's about to be unresolved,

but, you know, the case is, what is it, getting onto seven years old, eight years old?

MR. RAOFIELD: Yes, your Honor, that makes perfect sense to me. From my client's perspective, the one piece of that, and I wasn't quite clear enough, the one piece of that that my client does care about, of course, is that we've negotiated our discovery cutoff of September 30, and if the parties go through that and conclude that and then subsequently there's a First Circuit ruling, we think that it ought to be done, party discovery ought to be done by September 30th, and whatever causation -- right, the way I think of it, your Honor, is pretty simple.

I don't think plaintiff's attorneys tend to say I'm concerned about having too much proof of causation. If they're going to take causation discovery of Janssen, as they're doing, they ought to take robust causation discovery so we don't get a First Circuit ruling, and then they come back and say, well, this is totally unexpected, now we need a whole bunch of new custodians and depositions and everything, we ought to just do party discovery once.

THE COURT: Well, party discovery, I think that's right, again, and I could be missing something here, but I don't see any reason why that would be affected by the causation standard as a practical matter, but if the independent medical decisions of 100 different medical

providers, if that's now relevant, we have to figure out what we do with that.

MR. RAOFIELD: Understood, your Honor.

THE COURT: And that may change, you know, the whole pathway here, so I don't have an easy answer, I don't have a padded answer. I'm not going to set a deadline now on the assumption that nothing is ever going to change, you know --

MR. RAOFIELD: Sure.

THE COURT: -- and put people in difficult positions. Having said that, I want to make progress. I'd like to have some targets here.

MR. LEOPOLD: Your Honor, and our goal to complete as much of the discovery that we can certainly on this issue related to the defendant and then follow the road map whatever potentially the First Circuit does because we just don't know, they could rewrite some of the law or follow your Honor's law or something else, and then we'll have a road map of what to do thereafter.

THE COURT: And there's already a conflict in the circuits. It could get worse from there, but let's do this. I'm going to permit you -- you can do what you want, but three weeks from today -- let me call up the calendar. So by April the 3rd, you can file a submission in any form you see fit setting forth what you think the timetable ought to look like going forward with whatever caveats you think you want to bake

into that.

I will look at that, and I will set a schedule that I think reflects the most sensible path as I see it subject to change as we go down the road.

MR. RAOFIELD: Your Honor, could I ask for one slight change to that?

THE COURT: Yes.

MR. RAOFIELD: And I hate to ask because I think it's totally reasonable. For personal reasons, I'm wondering if we could make April 3rd April 5th. Basically I'm thinking that this may involve -- it may be productive for the parties to have a meet and confer about this before we file, and I come back from a leave of absence on the 2nd, and so it would be helpful if we could have until Friday, the 5th.

THE COURT: I'm not sure it makes much difference, so I'm going to give you until Wednesday, the 10th. I mean, we're already all the way out to September. So it says on your application, it's a leave of absence, I'm very impressed by that, and why don't we reconvene a week later, the afternoon of April the 17th. That's Massachusetts school vacation week. Is that going to be a problem for anyone?

MR. LEOPOLD: No, your Honor, I don't believe so.

THE COURT: Matt, let's say 3:00 on Wednesday, April the 17th for a further conference. Okay.

MR. LEOPOLD: Your Honor, one housekeeping matter.

THE COURT: Yes.

MR. LEOPOLD: The parties have agreed on the number of interrogatories that we can have. We have three additional interrogatories that we want to serve, and I believe we're all in agreement that that's okay. Normally your Honor would like us to file a motion for leave to do that. Would you like that?

THE COURT: The motion is deemed filed and deemed granted.

MR. LEOPOLD: Okay, very good, thank you, your Honor. I appreciate your time.

04:22PM

THE COURT: All I ask is that I never have to read any of these interrogatories. It gives me kind of a PTSD from my big firm practice days.

MR. LEOPOLD: We'll do our best, your Honor.

THE COURT: All right. Is there anything else we can accomplish today? Mr. Leopold?

MR. LEOPOLD: I think we've covered a lot, and your Honor has been very helpful, thank you.

THE COURT: Mr. Raofield?

04:23PM

MR. RAOFIELD: I agree.

THE COURT: Thank you, and we'll see you in mid-April. Thank you, your Honor.

(Whereupon, the hearing was adjourned at 4:23 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I do hereby certify that the foregoing transcript, Pages 1 through 17 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 16-12182-FDS, THE UNITED STATES OF AMERICA ex rel. JULIE LONG vs. JANSSEN BIOTECH, INC., and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

Dated March 20, 2023.

s/s Valerie A. O'Hara
_____
VALERIE A. O'HARA
OFFICIAL COURT REPORTER